

Food and Drug Administration College Park, MD 20740

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JUN 1 7 2002

Mr. Robert C. Doster Senior Vice President of Scientific Affairs Enzymatic Therapy, Inc. 825 Challenger Drive Green Bay, Wisconsin 54311-8328

Dear Mr. Doster:

This is in response to your letter of May 31, 2002 responding to FDA's letter to Enzymatic Therapy, Inc. dated April 9, 2002. Our letter to you was in response to your submission to FDA pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)) for the products "Migracare" and "MygraFree."

Thank you for your response to our letter. FDA will carefully consider the information in your letter regarding the claims being made for other products that marketed similar to your products that were the subject of our April 9, 2002 letter. With respect to the specific claims being made for the products that you provided information on, as a matter of policy, FDA does not provide comment on the appropriateness of specific products or claims made on a product's label or in its labeling to parties other than the responsible manufacturer. Therefore, we are unable to comment on the specific product-related information you provided. However, the agency will evaluate the information you provided, and respond in a manner appropriate to the findings of its evaluation and consistent with available resources and enforcement priorities.

However, we want to make clear that the fact that products may be available in the marketplace that bear claims in their labeling that cause them to be unapproved drugs does not change the status of the claims or the products under the Act. As we stated in our previous letter, 21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. A firm using such claims in the labeling of its dietary supplements does so at the risk that the agency may take enforcement action against that product without prior notice. As we have state, the agency believes that the claims you were making for your products, including the names of the products, evidenced that the products were intended to treat, cure, prevent, or mitigate migraine headache, a disease.

975-0163

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Page 2 - Mr. Robert C. Doster

Please contact us if we may provide you with further assistance or if you have further questions on this matter.

Sincerely,

John B. Foret

Director

Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300 FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Minneapolis District Office, Office of Compliance, HFR-SW340

applia



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May 31, 2002

Mr. John Foret
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740-3835

RECEIVED
JUN 04 2002
BY:

Dear Mr. Foret:

We are writing to call your attention to dietary supplements on the market that have obvious derivations from "migraine" that serve to identify a population of consumers with a disease for which the products are intended.

Enzymatic Therapy, Inc. received a Courtesy letter dated April 9, 2002 regarding our products Migracare and MygraFree (copy attached). You referred Enzymatic Therapy, Inc. to CFR 101.93(g)(2)(iv)(A). You also stated that our products are intended to treat a disease, namely migraine headaches and that the use of the name of a disease or other words or terms related to a disease is an implicit claim that a product is intended to treat, prevent, or mitigate that disease. We are enclosing competitor information which does exactly the same, and would like an explanation as to how they are able to make such claims using a product name or term relating to a disease.

We bring this to your attention so that the FDA may properly address these issues and are looking forward to your response.

Sincerely,

Robert C. Doster

for at

Senior Vice President of Scientific Affairs

Enclosure

825 Challenger Drive Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com



Food and Drug Administration College Park, MD 20740

APR - 9 2002

Dr. Robert C. Doster Senior Vice President of Scientific Affairs Enzymatic Therapy, Inc. 825 Challenger Drive Green Bay, Wisconsin 54311

Dear Dr. Doster:

This is in response to your letters of March 14, 2002 and March 25, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submissions were for the products Enzymatic Therapy Migracare® and PhytoPharmica MygraFreeTM.

The products Enzymatic Therapy Migracare®and PhytoPharmica MygraFree™ use the claim "Dietary supplement to support healthy circulation in the brain." This claim, used in conjunction with the names of the products, Mygracare® and MygraFreeTM is an implied claim that your products are intended to treat a disease, namely, migraine headaches. The use of the name of a disease or other words or terms related to a disease is an implicit claim that a product is intended to treat, prevent, or mitigate that disease. See 21 CFR 101.93(g)(2)(iv)(A). The terms Migracare® and MygraFree™ are obvious derivations from "migraine" that serve to identify a population of consumers with a disease for which the products are intended. FDA considers a brand name that includes a disease name or a clearly recognizable derivation of a disease name to be a disease claim unless the context of the labeling as a whole makes clear that the name does not imply disease treatment or prevention because the product is intended for some other use. The names of these products, however, provide no indication of what other uses the products could be intended for and, moreover, include claims that are clearly related to one of the underlying predisposing clinical causes of migraine headaches. As such, the names of these products and the accompanying claims are disease claims.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products

Page 2 - Dr. Robert C. Doster

are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret

Director

Division of Compliance and Enforcement Office of Nutritional Products, Labeling and Dietary Supplements Center for Food Safety

Center for Food Safety and Applied Nutrition

Julin B. Jand

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300 FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Minneapolis District Office, Office of Compliance, HFR-MW240

Product Information



MigraDefense™



Description:

MIGRA DEFENSE ò Butterbur has properties which significantly support cranial blood vessels. It is also a muscle relaxant. ò The Butterbur in this product is guaranteed to contain no more than 5 ppm of pyrrolizidine alkaloids. ò Feverfew inhibits the production of prostaglandins which constrict and dilate cerebral blood vessels. ò White Willow contains the glucoside, salacin. ò Guarana has been added to help decrease cranial blood flow. ò Griffonia (which supplies 5-Hydroxytryptophan) has been added as a serotonin precursor. ò This natural herbal product provides a new, safe alternative.

Item#:

67507

Size:

60ct

Suggested Retail

\$16.99

Price:

Directions:

As a dietary supplement, take 2 Fast-Acting capsules as needed

(up to four daily).

Serving Size:

2 Capsule 30 Servings per container

Ingredients:	Amount per serving:	% Daily Value: +	
Magnesium (as magnesium oxide)	200 mg	50%	
Organic Feverfew (Tanacetum Parthenium) (aerial) (Guaranteed to contain a minimum of 2mg [0.7%] parthenolide)	350 mg	~	
Guarana (Paulina cupana) (seed)	200 mg	~ · · · · · · · · · · · · · · · · · · ·	
GP Butterbur (Petasites hybridus) (root extract) (Guaranteed to contain 15mg [15%] sequiterpenes [petasin, petasol, neo petasol and isopetasol derivatives])	100 mg	~	
White Willow (Salix alba) (bark)	100 mg	~	

Key to Ingredients:

~ = Daily Value not established.

^{+ =} Percent Daily Value is based on a 2,000 calorie diet.

Other Ingredients: Gela

Gelatin (capsule), cellulose

Other:

See product label for more information.

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Mygrafew (Feverfew), Nature's Way, 90 Tabs.

Excerpted from Nature's Way product description:

MygraFewParthenoildeMore Potent Than Other ExtractSuperior Shelf Stability

Standardized Feverfew Extract Helps maintain normal blood vessel tone.

Studies at the London Migraine Institute have increased interest in the parthenolide in Feverfew for its role in maintaining normal blood vessel tone. Feverfew helps maintain normal blood vessel bone by reducing platelet aggregation, serotonin release from platelets and blocking the formation of pro-inflammatory mediators.

New improves Mygrafew provides the level of parthenolide recommended by both Canadian and British health authorities for optimal results. Each tablet provides the **recommended level of 600 mcg** parthenolide in a once daily dosage.

New high potency Mygrafew is standardized to 5% parthenolide - 7X more potent than other feverfew extracts.

Mygrafew is the only feverfew extract with guaranteed parthenolide stability for three years.

Mygrafew is free of common food allergens such as yeast, milk, lactose, wheat, sugar, soy or corn.

Supplement Facts: Serving Size 1 Tablet Servings Per Container 90

Amount Per 1 Tablet %DV
Feverfew, dried extract (leaf) 12 mg **
12 mg standardized feverfew extract
delivering 600 mcg parthenolide (5% parthenolide).

Other Ingredients:

Dicalcium phosphate, cellulose, modified starch, modified cellulose, magnesium sterate, silica.

Recommended Use:

Take one tablet daily with water. Best results are obtained with continuous use.

Caution:

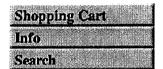
Not recommended for use by pregnant or lactating women or by children under two years of age. Certain individuals may experience oral discomfort or irritation when using this product. If irritation occurs, discontinue us immediately.**

Expiration date: Approximately 2 years after the date of purchase.

Brand: Nature's Way

^{**} Daily value not established.

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MygrAid Formula, 60 Cap

MygrAid Formula

Description: Advanced blend of current scientific research and traditional herbal medicine. Key ingredients include Feverfew extract and magnesium amino acid chelate, a superior form with improved absorption.

Usage: Mygraid uses Feverfew, to provide the active parthenolide proven to help maintain normal blood vessel tone by reducing platelet

aggregation, seratonin release from platelets and blocking the formation of pro-inflammatory mediators. Magnesium, essential for proper muscle function, and, Lavender and Linden Flowers, traditionally used by Europeans for head comfort.

Recommended Daily Dosage: Take one capsule three times daily with water, preferably with food.

The following list is for serving size of 1 capsule: Feverfew Leaves 100mg, Feverfew, dried extract 33.3mg, Lavender Flower 50mg, Linden Leaf & Flower 70mg, Magnesium Amino Acid Chelate 33.3mg, from Nature's Way.

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Feverfew Leaves, Nature's Way, 180 Capsules



" FEVERFEW LEAVES, Nature's Way, 180 Capsules

Our Feverfew is certified organically grown by Trout Lake Farm, Washington, and harves at their peak natural potency of .2% parthenolide. It is the same strain of Feverfew used in the studies at the London Migraine clinic.

Usage: Feverfew helps maintain normal blood vessel tone. Parthenolide also helps normalize the functions of platelets in the blood system by inhibiting platelet aggregation, reducing seratonin release from platelets and blocking the formation of pro-inflammatory mediators.

Recommended Daily Dosage: As an addition to the daily diet, take one capsule three times daily, preferably with food. Best results are obtained with continuos use.

The following list is for serving size of 1 capsule

USRDA Amount Primary Ingredients 0% 380 mg **Feverfew Leaves**

Other Ingredients: Gelatin "

Expiration date: Approx. 2 years after the date of purchase.

Sizes & Suggested Retail Price 180 capsules - \$15.49

NW-12808 8.50, 4 for \$31.00, 12 for \$87.00

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About Nature's Way

Company Summary



Located in the mountain valley of Springville, Utah, Nature's Way[®] is America's natural healthcare leader---specializing in the highest quality of natural medicines. Every product that bears the green Nature's Way leaf exceeds the most rigorous quality standards and testing procedures in the natural products industry. As a result, Nature's Way is more than just a range of products millions of people around the world use. It's the name they trust.

In total, Nature's Way provides over 350 products, including single herbs and herbal formulas, standardized herbal extracts, clinically proven phytomedicines, vitamins, minerals, probiotics, homeopathy, specialty formulas and all-natural over-the-counter medicines (OTCs). Operating from a 250,000 square-foot, pharmaceutical licensed manufacturing facility, we produce the world's highest quality natural healthcare supplements. In addition, we actively support worldwide environmental programs, use recycled packaging materials and sponsor alternative healthcare education.

Mission Statement

Our Mission is to benefit the quality of human health and promote positive health care choices by developing, manufacturing, and marketing preventative, curative and nutritive health care products of natural origin.

10 Mountain Springs Parkway • Springville, Utah 84663 801/489-1500 • Fax: 801/489-1700 Search IHerb.Com Show Order



Headache Relief, New Chapter, 30 Softgels.

Label Information:

" Headache Relief, New Chapter, 30 Hexane-Free Softgel Capsules

Full spectrum parthenolides from supercritically extracted feverfew, supporting normal cerebral vascular blood flow

25% naturally occurring Salicylic acid extracted from nature's most effective herbal salicin sourc

- High potency californidine source from natural poppy extracts
- Blocks the formation of inflammatory prostaglandins

A Supercritical New Chapter in Headache Relief

New Chapter's Headache Relief provides a potent and effective herbal method for achieving relief from one of life most common and unpleasant stressful experiences. Scientific research has clearly identified that the parthenolid within the feverfew flower have singular value in providing headache relief. New Chapter's exclusive supercritical CO2 extraction creates a uniquely high potency and stable parthenolide content enhanced with an array of nature best recognized and synergistic herbs to promote comfort and release from the common headache.

New Chapter's Supercritical Herbal Extracts "Supercritical" means Super Purity, Super Potency, Broad Spectrum, and No Chemical Solvents. We take nature's finest herbs and then extract and highly concentrate (a high as 250 to 1) their precious, full spectrum ingredients. We do not isolate single ingredients or spike our extrac with synthesized additives. We deliver the wisdom of nature, with the complexity and organic nuances of the natu herb preserved for you In fact, the supercritical process extracts more beneficial organic antioxidants and other compounds than any other extraction processes. And when you take New Chapter's supercritical extracts, neithe you nor the environment, have to contend with chemical solvents.

Supplement Facts

Serving size 1 Softgel Serving per container 30

One Softgel Contains

Feverfew (stem, leaf & flower), supercritical extract, (1% parthenolide-1.25 mg) 125 ma Green Tea (leaf), extract, (50% polyphenols-50 mg) (7% caffeine) 100 mg Wintergreen (leaf), extract, salicylic acid derivatives 75 mg Ginger, SBSC* (rhizome), certified organic, (minimum 20% pungent compounds-10 mg,4% zingiberene-2 mg) 50 mg 38 ma Meadowsweet (herb), extract, salicylic acid derivatives Purple willow (bark), (Salix purpurea), extract, salicylic acid derivatives 38 mg California Poppy (whole plant), extract 5:1 (leaf & essential oil), supercritical extract (23% total phenolic antioxidants [TPA] -2.3~mg) 20 mg Rosemary (leaf & essential oil), supercritical extract 10 mg (23% total phenolic antioxidants [TPA]-2.3mg) Ginger (rhizome), certified organic (post-supercritical ethanolic extract) 10 ma (3% pungent compounds-0.3mg) Lavender (flower), supercritical extract (25% linalool-2.5 mg) 10 mg Hops (strobiles), supercritical extract (35% humulones-1.7 mg) (12% 5 mg lupulones-0.6 mg) Valerian (root), (Valeriana officinalis & Valerians mexicanus) supercritical extract, (60% valepotriates-3mg) 5 mg

Other ingredients: olive oil-certified organic, yellow beeswax Capsule: gelatin, vegetable glycerine, purified water, carob

Our premium softgel capsules are prepared without any chemical solvents and are certified Kosher, Halal and prion free.

Warning: Women who are pregnant or contemplating pregnancy should consult with their health care provider before taking this product. "

Brand: NewChapter

30 Hexane-Free Softgel Capsules

Expiration Date: Approx. 2 years from the date of purchase.

Suggested Retail Price: \$21.95

iHerb Price: 35-45 % Off Suggested Retail Price. Always!

NC-4071 14.00, 4 for \$52.00, 12 for \$144.00

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Migra-Profen, Gaia Herbs, 60 Liquid Vegie Caps

Label information:

" Migra - Profen, Gaia Herbs, 60 Liquid-Filled Capsules Liquid Phyto - Caps with Phospholipase A2 and COX-2 Inhibitors

with Phospholipase A2 and COX-2 Inhibitors For Ultimate Relief of Headache Pain & Cramps 100% Vegetarian

A Dietary Supplement

Liquid Phyto Caps - Gaia Herbs' patented technology delivers a concentrated full spectrum alcohol-free liquid extract in a 100% vegetarian capsule. Now you can have the superior bioavailability and fast absorption of a liquid delivery system, from certified organic and ecologically wildcrafted herbs, in a convenient capsule.

Ecologically Wildcrafted • Certified Organic

Supplement Facts

Serving Size 1 Capsule Servings Per Container 60

Amount per 2 Caps	Amount per 2 Capsules					
Calories	14	laga serti la liberalit di tamang Talah				
Alcohol Free Concentrated Extract Of:						
Feverfew leaf (Tanacetum parthenium) *	300 mg	+				
Ch. Skullcap root (Scutellaria baicalensis) ***	110 mg	+				
Kava Kava (Piper methysticum) **	70 mg	+				
Valerian root (Valeriana officinalis) *	30 mg	+				
Jamaican Dogwood bark (Piscidia erythrina) **	20 mg	+				
Rosemary leaf, Supercritical Extr. (Rosmarinus off.)**	8 mg	+				
Ginger rhizome,						
Supercritical CO2 Extract (Zingiber off.) **	8 mg	+				
Standardized To Full Spectrum Activity Profile	· • • • • • • •					
Bioactivity Per 2 Capsules		mg Activity				
55% Kavalactones (from Kava Kava)	38.5 mg	+				
0.5% Parthenolide (from Feverfew)	1.2 mg	+				

⁺ Daily Value not established.

Other Ingredients: Vegetable glycerin, vegfetable cellulose.

Each 2 Capsules contain 5,000 mg crude herb equivalent.

Suggested Serving: Take 2 capsules with a small amount of warm water at the onset of pain and repeat 2-3 time at 15 minute intervals.

Caution: Not to be used during pregnancy or lactation. Keep away from children. Use only as directed on label. Safety sealed for your protection. Keep bottle capped at all times and store in a cool dry place. Natural separation may occur. This does not affect product quality. **

^{*}Certified Organic

^{**}Ecologically Wildcrafted

^{***}Untreated Chinese Origin

Expiration Date: Approx. 3 years from the date of the purchase.

Brand: Gaia Herbs

60 Liquid - Filled Capsules

Read more about this product at Gaia Herb's Web Site.

Suggested Retail Price: \$27.95

iHerb Price: 30-40 % Off Suggested Retail Price. Always!

GH-9880 21.00, 4 for \$78.00, 12 for \$218.00

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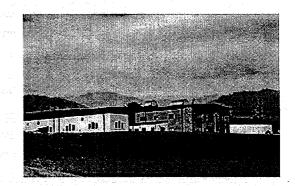
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Healthy Snacks, Herbal Teas, Stevia, Kashi

Specialty Supplements

Antioxidants, Probiotics, Bee Pollen, Glucosamine, Lutein, MSM, Royal Jelly

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Vitamins

Vitamins, Multivitamins

Weight Loss

Carb Blocker, Fat Burner, Cellulite Fighters, Thyroid Support, Appetite Control

Pet Products for Cats & Dogs

MigraGard® (30 capsules)

MigraGard® by Solaray contains the world's number one Feverfew. The high potency Feverfew (.7% parthenolide) in MigraGard® is certified organic.

Feverfew contains a range of compounds known as sesquiterpene lactones. Over 85% of these are a compound called parthenolide. Parthenolide helps prevent excessive clumping of platelets and inhibits the release of certain chemicals, including serotonin and some inflammatory mediators. According to migraine patients, feverfew reduces the severity, duration, and frequency of migraine headaches.

Ingredients - per capsule:

- Feverfew (Tanacetum parthenium) (leaves) (Guaranteed 2.45 mg [0.7%] parthenolide) 350 mg
- Feverfew (Tanacetum parthenium) (leaf) (Guaranteed 2.45 mg [0.7%] parthenolide) 350 mg

Other Ingredients: Gelatin (capsule), Feverfew Leaves and magnesium stearate Gelatin (capsule), Feverfew (leaves) and magnesium stearate

Solaray>MigraGard® (30 capsules)

8330 Retail price: \$9.99 Suzannes.com price: \$6.45

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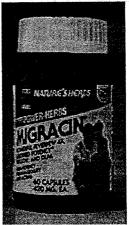
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Nature's Herbs Migracin - Certified Potency 60 Capsule



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Retail Price: \$\frac{12.99}{Your Price: \$\frac{7.98}{12.99}}



Description: Migracin is an herbal formulation that may be used to prevent migraine headaches and ease pain.

Instructions: As a dietary supplement for adults, take 2-6 capsules daily.

Additional Info: Our exclusive FreshCare System inhibits normal plant oxidation, maintaining product potency and extending freshness. It includes all-natural antioxidants in each capsule, oxygen-absorbing packets in each bottle, special air-tight seals and amber glass packing for umcompromised quality. Migracin is a natural-source supplement containing Power-Extract of Feverfew (Tanacetum parthenium), Certified Potency Extract of

White Willow (Salix alba) and DLPA (DL-Phenylalanine, an important amino acid). The Certified Potency Extract of White Willow adheres to stringent quality standards for potency and content of Salicin (active ingredient found naturally in Willow) assuring you of the same dependable quality every time. This Certified Potency symbol is your guarantee of dependable consistent quality and potency in every capsule every time! Only from Nature's Herbs.

Ingredients: Power-Extract of Feverfew 4:1(equivalent to 200mg of fresh feverfew)...50mg, Certified Potency Extract of White Willow Bark (standardized for 15% Salicin)...30mg, Power-Extract 5:1 and powder of White Willow Bark (equivalent to 1700mg fresh Willow)... 500mg, DLPA (DL-Phenylalanine)...250mg, Aromatic Natural Herbal Essential Oils

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Nature's Herbs

Migracin Plus - Certified Potency 30 Softgel



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Retail Price: \$-9.99 Your Price: \$ 6.14 Item # 042836



Description: Migracin Plus is suggested for the pain relief of migraine headaches.

Instructions: Take 2 capsules daily, preferably 1 with morning and evening meals.

Additional Info: Nature's Herbs, Certified Potency Power-Herbs Migracin Plus. Our exclusive FreshCare System inhibits normal plant oxidation, maintaining product potency and extending freshness. It includes all-natural antioxidants in each capsule, oxygen-absorbing packets in each bottle, special air-tight seals and amber glass packaging for uncompromised quality. This Certified Potency symbol is your guarantee of dependable consistent quality and potency in every capsule every time! Only from Nature's Herbs. Migracin Plus is a natural-source supplement containing Certified Potency Feverfew (tanacetum parthenium). A rich source of Sesquiterpene lactones, including a substance

called parthenolide, Migracin Plus uses standardized, stabilized Feverfew Extract assuring consistent potency of parthenolide in every softgel. In addition, Certified Potency White Willow Bark (standardized for salicin) and Magnesium have been added in just the right balance for a powerful, effective formula. Each softgel is preservative-free. Nature's Herbs, The Power to Feel Your Best! Since 1969.

Ingredients: Certified Potency Feverfew extract (standardized for 150mcg sesquiterpene lactones)...10.5mg, Certified Potency White Willow Bark Extract (standardized for 15% salicin)...25mg, Ginger Root Extract (standardized for 5% gingerols)...25mg, Magnesium...200mg, Vitamin E (d-alpha tocopherol)...400iu

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Nature's Herbs

Willowprin Max - Certified Potency 30 Capsule



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Retail Price: \$-10.79 Your Price: \$ 6.63 Item # 042489



Description: Willoprin contains White Willow Bark (Salix Alba) which has analgesic and anti-inflammatory properties and may alleviate pain, reduce fevers, help arthritis, rheumatism, diarrhea, pain, inflammation, heart disease, and delay cataract formation.

Instructions: As a dietary supplement, adults take 2-3 capsules every four hours as desired up to 18 capsules per day.

Additional Info: The highest quality, most potent and most effective form of White Willow Bark extract available. It is standardized at the highest concentration of naturally-balanced active principles while retaining and enhancing all the whole- plant synergistic benefits and is one of the world's finest and purest plant extracts. Faster -acting and more assimilable than ordinary White Willow.

Ingredients: Certified Potency White Willow Bark Extract...200mg (concentrated and standardized at 15% salicin (a natural constituents), equivalent to about 4000mg of Dry White Willow Bark, White Willow Bark 5:1...500mg (equivalent to 2500mg of white willow) White Willow Bark...200mg

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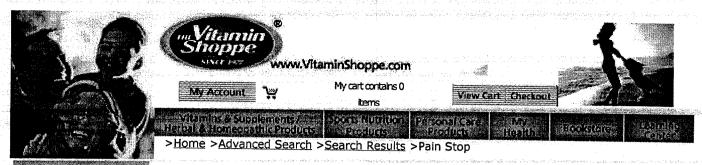
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Adults: 2 to 4 vegicap capsules as needed, up to 3 times Daily, preferably with food.

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